

Remarks

The following is a response to the Office Action dated September 18, 2006.

Claims 1-2, 4, 9, 20-21, 23 and 28 were rejected under 35 U.S.C. 102(e) as being anticipated by Crawford et al. (US 2002/0161336).

Among other limitations, independent claims 1 and 20 each recite a collar rotatably mounted directly on the distal portion of the needle hub. To ensure that such feature is clear, claims 1 and 20 each have been amended to recite that with such a rotatably mounted collar, the collar is "rotatable about said needle hub".

Crawford discloses a needle hub 60 to which a collar 90 is fixedly attached. Such fixed attachment of collar 90 to needle hub 60 is required, and indeed is an essential feature of Crawford, since Crawford requires that the orientation of the shield 140, which is hingedly attached to collar 90 by means of hook 115, has to be oriented in such a way that the bevel 46 of needle 44 that extends from needle hub 60 has to be at a given orientation. This is clearly disclosed in paragraph [0064] of Crawford where he states "Hub 60 then is joined with collar 90 by ultra-sonic welding techniques or any other bonding techniques, or mechanical fit, whereby rearward annular skirt 94 of collar 90 mates with the ribbed end 66 of the hub. ... Collar 90 is aligned with the intravenous end of needle 40 whereby the hook 114 is aligned with the bevel [up] of needle 40." That collar 90 is fixedly attached to hub 60 is further required insofar as sleeve 50 has to be rotated relative to collar 90, so that its proximal end 54 could be threaded to the forward skirt 92 of collar 90, by the respective threading of external thread 56 of sleeve 50 to the internal thread 97 of collar 90. In other words, if collar 90 were to be rotatable about needle hub 60, then sleeve 50 could not be threaded to collar 90, as clearly taught by Crawford et al. Thus, collar 90 has to be fixed attached to needle hub 60 not only for the alignment of the tip 60 of needle 40 with shield 90, but also the fitting of protective sleeve 50 to collar 90 to protect needle 40 prior to use. The instant invention, in contrast, has a collar that is rotatably mounted onto and rotatable about the needle hub.

Indeed, Crawford considers the combination of collar 90 and needle hub 60 to be a “needle hub” per se. This is disclosed for example in the Abstract where Crawford discloses “An IV shield is threadedly engaged with the distal end of the hub and protectively covers the piercing element. A hinged shield is hingedly mounted to the hub...” That hub 60 and collar 90 are considered together as a single hub (due to its welding or mechanical fit) is further taught by Crawford in his claims wherein each of the independent claims 1, 14 and 15 recites that an IV shield is threadedly engaged with the distal end of the hub. Also, claim 1 specifically recites “a protective cap removably mounted to said proximal end of said hub.” Thus, Crawford also teaches that his hub is in contact with the needle sheath 50. Not so with the instant invention which requires that the sheath not be in contact with the needle hub.

Accordingly, it is respectfully submitted that claims 1 and 20 each are not anticipated by Crawford.

Nor does Crawford anticipate dependent claims 4 or 23, insofar as each of those claims recites a groove formed circumferentially at the open end of the needle sheath and a rib formed circumferentially at the inner wall of the distal end of the collar. In contrast, Crawford teaches the forming of helical thread 56 and counter helical groove 97 at the sheath and collar, respectively. Circumferential groove and rib are not the same as helical thread and groove.

As for the §103 rejection of claims 8, 10 and 27 over the combination of Crawford and Landis (US 5,490,841), it is respectfully submitted that Landis fails to teach lips being “angled toward the interior of housing with the respective angles of said lips being varied along the length of said housing to effect guide for said needle to smoothly enter into said housing at an angle through said opening”, as required in claims 8 and 27. Such can readily be seen by comparing the angled slot opening 88 as shown in Fig. 10 of the instant application with Figs. 6-12 of the protective housing shown in Landis.

Claims 11, 13 and 15-17 were rejected under 35 U.S.C. 103 as being unpatentable over Johnson (US 2002/0010433) in combination with Gyure et al. (US 5,681,295) and Lockhart (US 2,693,183).

Johnson discloses an adapter 40 that has a housing 42 surrounding a male end 70, so that there is a recess 50 formed between housing 42 and male connector end 70. As best shown in Fig. 2d, the adapter 70 is press fit to a hub 18 to form a "rigidifying seal." Indeed, the crux of the Johnson invention is the forming of a rigidifying seal to support the outside diameter of hub 18 so as to prevent hub 18 from spreading and/or from cracking or breaking, and also allow the user to "manipulate more aggressively" the device. In addition, the housing 42 also provides for a fluid tight seal to prevent any fluid from leaking. See paragraph [0044]. That housing 42 forms a rigidified seal clearly means that Johnson does not intend to have any "window" or openings provided at housing 42. Otherwise, the purpose of the Johnson adapter being a seal would be totally defeated, both in terms of not rigidifying hub 18 since an opening clearly could not provide for a rigid support and could not provide a seal since it would allow fluid to escape from the adapter.

Gyure considers the annular flange 335 to be a part of hub 328, per shown in Fig. 12. This is disclosed in column 9, line 43 to column 10, line 16. In any event, as best shown in Fig. 12, note that needle cover 37 is in contact both with annular flange 335 at its open end, as well as with the smaller section of needle hub 328 where the shoulder portion of needle cover 37 is in contact with the rib of needle hub 328. In contrast, the instant invention, as set forth in claim 11, requires that the sheath not be in contact with the needle hub.

Lockhart discloses an ampule 40 fitted with a needle hub 50. As best shown in Fig. 6, a portion of needle hub 50 is grinded to form a notch 60 so that the double ended needle (identified by bores 63, 62) also has a part thereof removed to form an elongate slot 61. The needle hub 50 is then fitted into the ampule neck 43 (Fig. 7) so that notch 60 is sealed. See also the disclosure in column 4, lines 61-76. The fact that the ampule neck is made

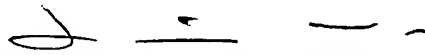
of transparent material allows the user to view blood that is being pumped into notch 60, when ampule 40 is pressed in the direction as indicated by reference numeral 40 in Fig. 4. The Lockhart window therefore does not enable this viewing of a luer connector, as the window opens directly to the notched-out portion of the needle.

In light of the above discussion with regard to Johnson, Gyure and Lockhart, it is respectfully submitted that those references could not be combined as suggested by the examiner inasmuch as the so-called window provided by Lockhart is not a window that would allow the viewing of a luer connector, as required in claim 11. So, too, that Johnson requires a press fitting of his housing 42 to hub 18 clearly contradicts the teachings of Gyure, which teaches the rotatable mounting of a collar 41 to a collar receiving recess 34 at needle hub 28. The combining of Johnson with Gyure clearly run counter to the respective expressed desired objectives of Johnson and Gyure, as Johnson requires a tight fit while Gyure requires a rotatable fit. Accordingly, it is respectfully submitted that claim 11, and the claims respectively depending therefrom, are patentably distinguishable over the combination of Johnson, Gyure and Lockhart.

The arguments above with respect to Crawford and Landis are equally applicable herein with respect to the rejection of claims 14 and 18.

In light of the foregoing, applicants respectfully submit that the instant invention is patentably distinguishable over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and pass the same to issue at an early date.

Respectfully submitted,



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Date: Dec 18, 2006